DEC 1 4 2011 K112057

Exhibit #2 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K112057

1. Date of Preparation: 18 NOV 2011

2. Sponsor
   Shanghai Kindly Enterprise Development Group Co., Ltd.
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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   Fax: 240-238-7587
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4. Proposed Device Identification

   a. Proposed Device Name: Sterile Hypodermic Syringe for single use, with/without needle
      Proposed Device Model: Luer slip (1, 2, 3, 5, 10, 20, 30, 35, 50 (ml)) and Luer lock (1, 2, 3, 5, 10, 20, 30, 35, 50 (ml))
      Classification: II
      Product Code: FMF
      Regulation Number: 21 CFR 880.5860
      Review Panel: General Hospital
      Intended Use Statement:
      The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

b. Proposed Device Name: Sterile Insulin Syringe for single use, with needle
Proposed Device Model: Fixed needle (0.3, 0.5, 1 (ml))
Classification: II
Product Code: FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital
Intended Use Statement:
The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-100, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.
The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-40, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

c. Proposed Device Name: Sterile Hypodermic Needle for single use
Proposed Device Model: Luer slip and Luer lock (18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G)
Classification: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital
Intended Use Statement:
The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration

5. Predicate Device Identification

a. 510(k) Number: K070936
Product Name: Welmed Hypodermic Syringe (various sizes)
Manufacturer: Welmed Inc.

b. 510(k) Number: K072739.
Product Name: Sterile Hypodermic Syringe for Single Use, without Needle
Manufacturer: Shandong Weigao Group Medical Polymer Products Co., Ltd.

c. 510(k) Number: K110421
Product Name: Disposable Insulin Syringe
Manufacturer: Wenzhou Wuzhou Import & Export Co., Ltd.

d. 510(k) Number: K070440
Product Name: BD Hypoint
Manufacturer: BD Medical-Pharmaceutical Systems

6. Device Description

Device Name	Intended Use	Nozzle	Volume	Material	Remark
Sterile Hypodermic Syringe for single use with/without Needle	The Sterile Hypodermic Syringe for Single Use with/without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Luer Slip	1,2,3,5,10,20,30,35,50(ml)	PP	With or Without Needle
		Luer Lock	1,2,3,5,10,20,30,35,50(ml)		
Sterile Insulin Syringe for single use with Needle	The sterile Insulin Syringe for single use with needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.	Fixed Needle	0.3,0.5,1(ml)	PP	With Fixed Needle
Sterile Hypodermic Needle for single use	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	Luer Slip Luer Lock	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Stainless Steel	----

7. Summary Comparing the Technological Characteristics

The proposed devices and predicate devices have the same classification information, intended use, principle of operation, performance, biocompatibility, materials, and sterilization specifications. Both the proposed devices and predicate devices meet the requirements of ISO 10993, ISO 7886-1, ISO 8537, ISO 7864 and ISO 9626. Although there is some difference in syringe volumes and syringe nozzle, such difference will not affect the safety and effectiveness of the proposed devices. So the proposed devices are substantially equivalent to the predicate devices through the comparisons between the proposed devices and predicate devices.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed devices met all design specifications as were Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed devices comply with the following standards:

a. For Sterile Hypodermic Syringe for single use, with/without needle

ISO 7886-1:1993 Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use;
ISO 594:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements
ISO 594:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings

b. For Sterile Insulin Syringe for single use, with needle

ISO 8537:2007 Sterile single-use syringes, with or without needle, for insulin;
ISO 594:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements
ISO 594:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings

c. For Sterile Hypodermic Needle for single use

ISO 7864:1993 Sterile hypodermic needles for single use;
ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices/Amendment: 2001
ISO 594:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements
ISO 594:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings

9. Substantially Equivalent Conclusion

The proposed device, Sterile Hypodermic Syringe for single use, with needle, is determined to be Substantially Equivalent (SE) to the predicate device, Welmed Hypodermic Syringe (various sizes), K070936, in respect of safety and effectiveness.

The proposed device, Sterile Hypodermic Syringe for single use, without needle, is determined to be Substantially Equivalent (SE) to the predicate device, Sterile Hypodermic Syringe for Single Use, without Needle, K072739, in respect of safety and effectiveness.

The proposed device, Sterile Insulin Syringe for single use with needle, is determined to be Substantially Equivalent (SE) to the predicate device, Disposable Insulin Syringe, K110421, in respect of safety and effectiveness.

The proposed device, Sterile Hypodermic Needle for single use, is determined to be Substantially Equivalent (SE) to the predicate device, BD Hypoint, K070040, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shanghai Kindly Enterprise Division Group Company
C/O Ms. Diane Hong
MID-Link Consulting Company Limited
P.O. Box 237-023
Shanghai
China 200237

DEC 1 4 2011

Re: K112057
Trade/Device Name: Sterile Hypodermic Syringe for Single use with/ without Needle, Sterile Hypodermic Needle for Single use, Sterile Insulin Syringe for Single use with Needle (U-40), Sterile Insulin Syringe for Use with Needle (U-100)
Regulation Number: 12 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: November 18, 2011
Received: November 29, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #1 Indications for Use Statement

510(k) Number: K112057

Device Name: Sterile Hypodermic Syringe for Single Use with/without Needle

Indications for Use:

The sterile hypodermic syringe for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

12/19/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112057

Indications for Use Statement

510(k) Number: K112057

Device Name: Sterile Insulin Syringe for Single Use with Needle (U-100)

Indications for Use:

The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-100, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

☐PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

12/14/11

ivision Sign-Off)
ision of Anesthesiology, General Hospital
ection Control, Dental Devices

510(k) Number: K112057

Indications for Use Statement

510(k) Number: K112057
Device Name: Sterile Insulin Syringe for Single Use with Needle (U-40)

Indications for Use:

The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-40, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

☐PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/14/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112057

Indications for Use Statement

510(k) Number: K112057
Device Name: Sterile Hypodermic Needle for Single Use

Indications for Use:

The sterile hypodermic needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/14/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112057